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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/324,343	06/02/1999	JOHAN H. GEERKE	ALZA-0022 ARC-2865-R3	1409

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EXAMINER	
SHARAREH, SHAHNAM J	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/324,343	GEERKE ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Reply filed on November 4, 2004 has been entered. Claims were subject to a restriction requirement. On the April 24, 2000 submission, Applicant elected Group III, claims 18-31 for the prosecution. Claims 1-17 stand withdrawn as they are directed to non-elected inventions.

Applicant's arguments have been fully considered but are not found persuasive for the reasons described below.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al US Patent 5,248,310 in view of Wong et al US Patent 5,785,994.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that the Barclay patent teaches a two-layer tablet and the Wong patent teaches a three-layer tablet. Accordingly, Applicant concludes that there is no motivation to combine the cited patents to reach the instantly claimed invention as neither of the cited references teach a tablet that has a two drug-containing layer. (see Remarks at page 10-11).

As the initial matter, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231

USPQ 375 (Fed. Cir. 1986). Here, all elements of the claims have been described by the cited references. Examiner has further explained a motivation to modify the cited patents to reach the instant claims. Accordingly, the rejection is based on the combined teachings of the references. Therefore, mere failure of one of the references to meet all elements of the instant claims does not render the instant claims patentable.

Moreover, Applicant's arguments are not commensurate with the scope of the claims because the instant claims do not require a separate two separate drug layers. The recitation of claims 22-27 is directed to tablets that contain a drug layer wherein a colorant appears to be concentrated in a specific region of said drug layer. There is no limitation in the instant claims requiring the drug ingredient of the instant drug layers to be different or distinct by any degree of concentration or chemical action. Therefore, Applicant's interpretation of two separate drug layers is not commensurate with the scope of the claims.

Further, Applicant's argues that the instant claims are directed to such tablets that have two drug layers and the Wong patent includes only one drug layer is not persuasive, because adding different drug layers is well within the ordinary level of a skilled artisan. (see Remarks at page 11, 1st para.).

Wong teaches a three or more layered tablet that provides a varying pattern of drug release (see abstract, col 2, lines 4-20). Such pattern is achieved by drug concentrations in each layer of Wong's formulation. Thus, adding additional drug layers is well within the scope of Wong's teachings. Therefore, adding different drug or polymer layers into a formulation is well within purview of one of ordinary skill in the art.

Furthermore, Examiner states that during patent examination, the pending claims are given their broadest interpretation and viewed in light of the specification. (see MPEP 2111-2111.07). Having such standard in mind, Examiner did not interpret the point of novelty for which applicant is seeking protection to be methods of preparing a one, two or three layer tablet. Rather, Examiner considering the entire language of claim viewed the point of novelty in the instant claims to be directed to the use of colorant in multilayer tablets for purposes of determining the formulation orientation. See for example, page 1 of the instant specification at lines 10-20 for such vision. Here, given the combined teachings of Barclay and Wong, the claimed point of novelty is an obvious modification of what is already known in the art.

Contrary to Applicant's position, the issue before the Examiner was not whether the prior art teaches a two or three layer tablet. Rather, whether colorants or coloring agents were known in the art to be used for detecting the formulation orientation in any multilayer tablet formulation. Examiner believes that the combined teachings of Barclay and Wong render such claimed invention obvious.

As stated in the previous Office Action, Barclay clearly shows that coloring agents are used in the art for determining the formulation orientation. (see Col 17, lines 20-56). Barclay describes the drug layer to have a white color (see col 17, lines 30-33). Barclay teaches the non-drug polymer layer to contain a reddish-brown color (see col 17, lines 40-44). Barclay then compresses the drug and non-drug layer together and coats the resultant solid osmotic tablet with a translucent coating. (see col 17, lines 39-51). Barclay then detects or observes the white drug-containing layer from the reddish-

brown polymer- layer in the tablet. (see col 17, lines 52-54). After detecting which side of the tablet contains the drug layer (in another words, detecting the orientation of the tablet), Barclay chooses to drill a passage whole through the drug-containing layer for delivering the drug from the osmotic tablet. (see cool 17, lines 55-57). Therefore, Barclay teaches the use of colorant for purposes of detecting orientation of a two layered osmotic tablet.

Barclay only fails to expclitly teach a three layer tablet. However, preparing a two or three layer osmotic tablet is well within the level of an ordinary skill in the art. For example, Wong teaches a three layer osmotic tablet using the same drugs, same polymeric moieties and same drilling technique as Barclay.

Barclay employs aspirin, steroids etc... (see col 11, lines 1-65, examples 1, 3 and 5). Wong also employs the same drugs (see Wong at col 10-col 11, lines 7-8).

Barclay describes hydrophilic polymers and hydrogels as suitable polymeric units (see col 13, lines 23-67). Wong also teaches the same polymeric moieties (see Wong at col 12, lines 44-col 13, line, 65).

Barclay teaches osmagents such as magnesium sulfate etc...(see col 13, lines 4-20). Wong teaches the use of the same osmagents (see col 5, lines 33-50).

Barclay uses the ferric oxide as the colorant in the polymeric layer (see example 2). Wong also uses ferric oxide as a colorant in his polymeric layer (col 17, lines 18-26).

The only difference between Barclay and Wong is that Barclay teaches a two layer osmotic tablet, but Wong teaches a three layer osmotic tablet.

Wong essentially teaches the same tablets as Barclay. Except that Wong is a three or more layered tablet that provides a varying pattern of drug release. (see abstract, col 2, lines 4-20). Such pattern is achieved by drug concentrations in each layer of Wong's formulation.

As previously stated, Examiner did not view the number of layers to be the point of novelty at issue, because as taught by Barclay and Wong, adding layers to an osmotic delivery system is conventional and a matter of design choice to alter pattern of drug release.

The issue before the Examiner was whether one of ordinary skill in the art would have been motivated to use coloring agents in a three-layer tablet formulation for determining the orientation of the tablet. Applicant has not provided any evidence to show why the use of colorant taught by Barclay may not be practiced in Wong's methods of preparing three layer osmotic tablets. Accordingly, Applicant has not met the burden of showing non-obviousness.

Claims 18-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay and Wong and further in view of Rork US Patent 5,582,838 and Misra US Patent 5,422,831.

Applicant's arguments with respect to this rejection have been fully considered but are not persuasive.

Applicant argues that Barclay does not teach two- drug-containing layers and none of the secondary references remedy such shortcomings. (see Remarks at page 11).

In response, as argued above, Examiner states that the point of novelty in the instant claims were viewed to hinge upon whether two drug-containing layer would offer a different outcome when a colorant is used in it for the purposes of detecting the orientation of the formulation. Rather, Examiner viewed whether a coloring agent can be used in determining the orientation of a formulation, regardless of the number of layers that are contained in the tablet.

Moreover, the instant composition or method claims do not exclude the formulations of Rork. Indeed, Rork states that his tablets may contain multiple layers (see col 7, lines 40-67). Thus, adding additional drug or non-drug layer is well within the level of ordinary skill in the art and is viewed to be a matter of design choice and the desired outcome.

Applicant also argues that the rejection is based an improper "obvious to try" standard set forth in In re O'Farrel, 853 F.2d 894, 902, 7 USPQ 2d 1673 (Fed. Cir. 1988) (see Remarks at page 11, last para.).

Contrary to Applicant's arguments the rejection is not based on an obvious to try, rather on the *prima facia* obviousness standard. As explained in *In re O'Farrell*, improper rejection of claims on an obvious to try reasoning has been directed mainly at two kinds of error:

(1) Cases that, what was "obvious to try" would have vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. E.g ., *In re*

Geiger , 815 F.2d at 688, 2 USPQ2d at 1278; *Novo Industri A/S v. Travenol Laboratories, Inc .,* 677 F.2d 1202, 1208, 215 USPQ 412, 417 (7th Cir. 1982); *In re Yates*, 663 F.2d 1054, 1057, 211 USPQ 1149, 1151 (CCPA 1981).

(2) Cases that , what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *In re Dow Chemical Co* ., 837 F.2d, 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985); *Hybritech, Inc. v. Monoclonal Antibodies, Inc* ., 802 F.2d 1367, 1380, 231 USPQ 81, 90-91 (Fed. Cir. 1 986), cert. denied , 107 S.Ct. 1606 (1987); *In re Tomlinson*, 363 F.2d 928, 931, 150 USPQ 623, 626 (CCPA 1966).

However, neither of these situations applies here. Using a colorant to distinguish different layers in an osmotic tablet does not require varying all parameters described in the prior art. In fact, Barclay specifically describes how to use the colorants in different layers of an osmotic tablet for determining the orientation of the formulation.

Nor is the instant claims directed to a new technology or a general approach to a field of experimentation. Barclay's patent was issued in 1993. Accordingly, the art of using coloring agents in osmotic agents for purposes of detecting the orientation of such agents is not viewed a new technology.

Thus, Applicant's reliance on *In re O'Ferrell* is misplaced as the rejection employs prima facia analysis to reject the presented claims. For obviousness under §103, all that is required is a reasonable expectation of success. *In re Longi*, 759 F.2d

887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985), the combined teachings of the references set forth a reasonable expectation of success.

Conclusion

No claims are allowed. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, JD, PharmD, whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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